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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,837	06/22/2006	Sjoerd Henricus Van Der Burg	0470-061908	6307

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,837	VAN DER BURG ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-44* is/are pending in the application.

4a) Of the above claim(s) *23-31 and 41-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 June 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/16/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group II, claims 32-40, SEQ ID NO: 1 and a tumor antigen, in the reply filed on April 28, 2009 is acknowledged. The traversal is on the ground(s) that a search and examination of all claims may be made without imposing a serious burden because a search for one sequence would necessarily include a search of the others. Applicant argues that all of the sequences are PNA probes capable of bindings to HPV DNA. This is not found persuasive because lack of unity (for a national stage filing) does not hinge on search burden. Regardless, a search for each sequence would be a serious burden because they are different in amino acid content. While the sequences may be commonly referred to as PNA probes, they are structurally distinct molecules that must be searched separately. Likewise, the relatedness of the groups is acknowledged, however, lack of unity rules apply in this situation as does the right to rejoinder should the product claims be found allowable. (See page 4 of the restriction requirement for the details of right to rejoinder.) The requirement is still deemed proper and is therefore made FINAL.

2. Claims 23-44 are pending. Claims 23-31 and 41-44 are withdrawn from consideration being drawn to non-elected subject matter. Claims 32-40 are under examination. Note that Applicant's election of SEQ ID NO: 1, an HPV antigen, is not commensurate with the election of a tumor antigen in claim 32. While the E7 protein is associated with HPV-induced dysplasia and transformation into cervical carcinoma, it is not itself a tumor antigen. Therefore, the election of SEQ ID NO: 1 is also an election of an antigen of a pathogen in claim 32. The embodiment of a tumor antigen in claim 32 is withdrawn from consideration, as are SEQ ID NO: 2-6.

Specification

3. The specification is objected to because there are amino acid sequences throughout the specification that are not identified with a sequence identifier. Correction is required.

Drawings

4. The drawings are objected to because Figure 1 recites an amino acid sequence that is not referenced by a sequence identifier. In lieu of a new/amended drawing, Applicant may amend the specification to include the SEQ ID NO in the description of the figures/drawings. Correction is required.

Claims Summary

5. The claims are drawn to a composition comprising a synthetic protein (chemically synthesized, see page 5, lines 10-22 of the specification). Note that the Office does not consider the process by which the protein is made/obtained to be a patentable distinction, as long as the protein is structurally and thus functionally the same. The protein comprises an amino acid sequence that is at least 80% identical to 46 contiguous amino acids of a naturally occurring antigen of a pathogen, specifically, HPV-16 E7 antigen (SEQ ID NO: 1). The composition does not contain any nucleic acid encoding the antigen. The composition may further comprise a pharmaceutically acceptable carrier, anti-CD40 antibodies, and/or adjuvant that activates dendritic cells. The composition is used as a vaccine.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32-36, 38 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim *et al.* (*Cancer Research*, December 15, 2002, 62:7234-7240, "Kim"). The claims are summarized above. Kim discloses the administration of E7 protein (full length, 98 amino acids) and CpG-oligodeoxynucleotide (CpG-ODN, an adjuvant that naturally activates dendritic cells) to mice and subsequent protective immunity against challenge with HPV-16 (E6/E7) immortalized tumor cells (abstract). The sequence of the protein is expected to be at least 80% identical to 46 amino acids of SEQ ID NO: 1 (HPV-16 E7 protein) because Kim's E7 protein was not mutated. Although Kim did not synthetically produce the protein, it is expected to have the same properties and at least 80% identity to SEQ ID NO: 1. The E7 protein was stabilized in buffers (pharmaceutically acceptable carrier) and administered as a vaccine (pre-challenge). Although Kim does not note the absence of nucleic acid encoding E7, none is expected to be present in Kim's composition because Kim purifies the protein.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim as applied to claim 32 above, and further in view of Zwaveling *et al.* (*The Journal of Immunology*, 2002, 269:350-358, "Zwaveling") and Turner *et al.* (*The Journal of Immunology*, 2001, 166:89-94, "Turner"). Claim 39 is directed to a composition comprising an antigen that comprises an amino acid sequence that is at least 80% identical to 46 contiguous amino acids of a naturally occurring antigen of a pathogen, and additionally comprises anti-CD40 antibodies. The teachings of Kim are summarized above. Kim does not teach or suggest the use of anti-CD40 antibodies in combination with the HPV-16 E7 protein/CpG-ODN construct.

However, it would have been obvious to include an agent that activates dendritic cells, such as anti-CD40 antibodies. One would have been motivated to activate the DCs in order to achieve a greater immune response. Zwaveling teaches that anti-CD40 antibodies are DC-activating agents. Given that Kim uses the CpG-ODN for activating DCs, one would have had a reasonable expectation of success that the inclusion of another DC-activating agent, such as anti-CD40 antibodies, would have resulted in the activation of more DCs than the CpG/ODN construct alone. Further, Turner teaches that anti-CD40 antibodies induce antitumor and antimetastic effects in tumor-bearing mice (abstract). Given the positive effects of anti-CD40 antibodies, one would have also been motivated to include the antibodies in a treatment composition/regimen as part of a multi-faceted approach. Therefore, the claimed embodiment would have been obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

8. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B Chen/
Primary Examiner, Art Unit 1648